K073652

5. 510(k) SUMMARY

The Date Prepared : December 14th, 2007

MAR 20 2008

The Company :

NAKAMURA DENTAL HANDPIECE MFG. CO., LTD.
59-2 Minami-cho, Itabashi-ku, Tokyo 173-0027, Japan
Phone : 813-3955-5307 / Fax : 813-3955-5309
E-mail : shinich@mvj.biglobe.ne.jp
The Establishment Registration Number : 9614686
Owner / Operator ID Number : 0910791

The Contact :

Charlie Ito / CEO
HEAD DENTAL CORPORATION
17972 Sky Park Circle, Suite J, Irvine, CA 92614-6409
Phone : 949-474-0176 / Fax : 949-474-1736
E-mail : HEADDental@aol.com
The Establishment Registration Number : 2080470

The Device Trade Name :

ND LOWSPEED AIRMOTOR HANDPIECE (SEVERAL MODELS)
Model Number : MD-50M / MD-50B / MD-20M / MD-20B / MP-40M

The Product Code : EFB

Any FDA Document numbers associated with prior formal correspondence with FDA :

B000016

The Common or Usual Name : Air-Powered Low Speed Handpiece

The Predicate Device :

510(k) Number : K070869
Trade or Propriety or Model Name : PROPHY STAR 3 HYGIENE HANDPIECE, MODEL 264422
Manufacturer : DENTALEZ, INC.

Description / Intended Use :

ND air powered low speed airmotor is used to power various U-type attachment which helps dental clinician perform the hygiene dentistry work. All the devices are autoclavable.

Substantial Equivalence :

ND LOWSPEED AIRMOTOR HANDPIECE as submitted is substantially equivalent to PROPHY STAR 3 HYGIENE HANDPIECE, MODEL 264422, currently being marketed by DENTALEZ INC. Materials used to manufacture the components are similar. Means of operation is identical ; compressed air powers a variable speed rotary vane motor to provide power for various dental procedures. The performance specification is virtually identical. The slight difference between the predicate device and the submitted device is color, size and weight.

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5. 510(k) SUMMARY

The Date Prepared : December 14th, 2007

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Phone : 949-474-0176 / Fax : 949-474-1736
E-mail : HEADDental@aol.com
The Establishment Registration Number : 2080470

The Device Trade Name : ND LOWSPEED AIRMOTOR (SEVERAL MODELS)
Model Number : ME-20M / ME-20B / ME-80M / ME-80B

The Product Code : EFB

Any FDA Document numbers associated with prior formal correspondence with FDA :
B000016

The Common or Usual Name : Air-Powered Low Speed Motor

The Predicate Device :

510(k) Number : K896878
Trade or Propriety or Model Name : Dual Low Speed Motor
HANDPIECE SYSTEM WITH MOTOR
Manufacturer : MICRO MOTORS, INC.

Description / Intended Use :

ND air powered low speed airmotor is used to power various attachment which helps dental clinician perform various dental procedures.

Substantial Equivalence :

ND LOWSPEED AIRMOTOR as submitted is substantially equivalent to HANDPIECE SYSTEM WITH MOTOR (SEVERAL MODELS), currently being marketed by Micro Motors Inc. Materials used to manufacture the components are similar. Means of operation is identical ; compressed air powers a variable speed rotary vane motor to provide power for various dental procedures. The performance specification is virtually identical. The slight difference between the predicate device and the submitted device is color, size and weight.

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5. 510(k) SUMMARY

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Phone : 949-474-0176 / Fax : 949-474-1736
E-mail : HEADDental@aol.com
The Establishment Registration Number : 2080470

The Device Trade Name :
ND HIGHSPEED AIRTURBINE HANDPIECE (SEVERAL MODELS)
Model Number : TCP-450M / TCP-450B / TCP-350M / TCP-350B / TC-40PM / TC-40PB / TC-35YM / TC-35YB

The Product Code : EFB

Any FDA Document numbers associated with prior formal correspondence with FDA :
B000016

The Common or Usual Name : Air-Powered High Speed Handpiece

The Predicate Devices :
510(k) Number : K863677
Trade or Propriety or Model Name : TRADITION HIGHSPEED HANDPIECE
Manufacturer : MIDWEST

Description / Intended Use :
ND highspeed airturbine handpiece is an air-powered dental handpiece for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restoration and polishing teeth. All the devices are autoclavable.

Substantial Equivalence :

ND HIGHSPEED AIRTURBINE HANDPIECE as submitted is substantially equivalent to TRADITION HIGHSPEED HANDPIECE , currently being marketed by MIDWEST. Materials used to manufacture the components are similar. Means of operation is identical ; compressed air powers a variable speed impeller to provide power for various dental procedures. The performance specification is virtually identical. The slight difference between the predicate device and the submitted device is color, size and weight.

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5. 510(k) SUMMARY

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Phone : 949-474-0176 / Fax : 949-474-1736
E-mail : HEADDental@aol.com
The Establishment Registration Number : 2080470

The Device Trade Name : ND STRAIGHT NOSECONE (SEVERAL MIDELS)
Model Number : ES-30A / ESG-30AR / MWS-30A

The Product Code : EGS

Any FDA Document numbers associated with prior formal correspondence with FDA :
B000017

The Common or Usual Name : Straight Angle Dental Handpiece Attachment

The Predicate Device :

510(k) Number : K792445
Trade or Propriety or Model Name : MW STRAIGHT ATTACHMENT
Manufacturer : MIDWEST

Description / Intended Use :

ND straight nosecone is powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. ES-30A is E-type 1:1 ratio, ESG-30AR is E-type 4:1 ratio, and MWS-30A is Midwest-type 1:1 ratio. All the devices are autoclavable. All the devices accepts 2.35mm (3/32") standard burs and can have prophy angles mounted.

Substantial Equivalence :

ND STRAIGHT NOSECONE as submitted is substantially equivalent to MW STRAIGHT ATTACHMENT, currently being marketed by NIDWEST. Materials used to manufacture the components are similar. Means of operation is identical ; powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. The performance specification is virtually identical. The difference between the predicate device and the submitted device is ratio (ESG-30AR 4:1) and connection-type (ES-30A and ESG-30AR are E-type).

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5. 510(k) SUMMARY

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Phone : 949-474-0176 / Fax : 949-474-1736
E-mail : HEADDental@aol.com
The Establishment Registration Number : 2080470

The Device Trade Name : ND E-TYPE CONTRA ANGLE (SEVERAL MODELS)
Model Number : EC-20L / EC-30BL / EG-20L / EGG-20L

The Product Code : EGS

Any FDA Document numbers associated with prior formal correspondence with FDA :
B000017

The Common or Usual Name : E-type Contra Angle Dental Handpiece Attachment

The Predicate Device :

510(k) Number : K962540
Trade or Propriety or Model Name : E-TYPE CONTRA ANGLE NAC-E
Manufacturer : NSK NAKANISHI, INC.

Description / Intended Use :

ND e-type contra angle is powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. EC-20L and EC-30BL are 1:1 ratio, EG-20L is 4:1 ratio, and EGG-20L is 16:1 ratio. All of the devices are autoclavable.

Substantial Equivalence :

ND E-TYPE CONTRA ANGLE as submitted is substantially equivalent to E-TYPE CONTRA ANGLE NAC-E, currently being marketed by NSK NAKANISHI, INC. Materials used to manufacture the components are similar. Means of operation is identical ; powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. The performance specification is virtually identical. The slight difference between the predicate device and the submitted device is color, size and weight. The 4:1 and the 16:1 speed ratio are also available, in addition to the 1:1.

K073652

5. 510(k) SUMMARY

The Date Prepared : December 14th, 2007

The Company :
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Phone : 949-474-0176 / Fax : 949-474-1736
E-mail : HEADDental@aol.com
The Establishment Registration Number : 2080470

The Device Trade Name : ND U-TYPE PROPHYLAXIS ANGLE (SEVERAL MODELS)
RA-10PS / RA-10PK / RA-50PS / RA-50PK / RA-10PS / RA-10PK /
RA-50PS / RA-50PK / DC-10L / DU-20L / DU-20L

The Product Code : EGS

Any FDA Document numbers associated with prior formal correspondence with FDA :
B000017

The Common or Usual Name : U-type Contra Angle Dental Handpiece Attachment

The Predicate Device :

510(k) Number : K790722
Trade or Propriety or Model Name : PROHYLAXIS ANGLE
Manufacturer : YOUNG DENTAL MANUFACTURING CO, LLC.

Description / Intended Use :

ND u-type prophylaxis angle is used mounted on U-type nose attachment powered by either lowspeed airmotor or electric micromotor for hygiene dentistry work. All the devices are fully autoclavable.

Substantial Equivalence :

ND U-TYPE PROPHYLAXIS ANGLE as submitted is substantially equivalent to PROPHYLAXIS ANGLE, currently being marketed by YOUNG DENTAL MANUFACTURING CO. Materials used to manufacture the components are similar. Means of operation is identical ; it is used mounted on U-type nose attachment powered by either lowspeed airmotor or electric micromotor for hygiene dentistry work. All the models are fully autuclavable. The slight difference between the predicate device and the submitted device is color, size and weight.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nakamura Dental Manufacturing Company, Limited
C/O Mr. Charlie Ito
Chief Executive Officer
Head Dental Corporation
17972 Sky Park Circle, Suite J
Irvine, California 92614-6409

MAR 2 0 2008

Re: K073652
Trade/Device Name: ND Low Speed Airmotor (Several Models)
Model Number: MD-50M / MD-50B / MD-20M / MD-20B / MP-40M / ME-20M / ME-20B / ME-80M / ME-80B

ND U-Type Prophylaxis Angle (Several Models)
Model Number: RA-10PS/ RA-10PK / RA-50PS / RA-50PK / RA-10PS / RA-10PK / RA-50PS / RA-50PK / DC-10L / DU-20L / DU-20L

ND E-Type Contra Angle (Several Models)
Model Number: EC-20L / EC-30BL / EG-20L / EGG-20L

ND E-Type Straight Nosecone (Several Models)
Model Number: ES-30A / ESG-30AR / MWS-30A

ND Highspeed Airturbine Handpiece (Several Models)
Model Number: TCP-450M / TCP-450B / TCP-350M / TCP-350B / TC-40PM / TC-40PB / TC-35YM / TC-35YB

Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB, EGS
Dated: December 14, 2007
Received: December 26, 2007

Dear Mr. Ito:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket

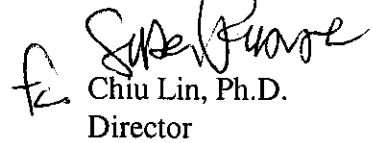
approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

4. Indications for Use

510(k) Number (if known) : K073652

Device Name : ND LOW SPEED AIRMOTOR (SEVERAL MODELS)
Model Number : ME-20M / ME-20B / ME-80M / ME-80B

Product Code : EFB

Any FDA Document numbers associated with prior formal correspondence with FDA : B000016

Indications for Use :

ND air powered low speed airmotor is used to power various attachment which helps dental clinician perform various dental procedures. All the devices are autoclavable.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073652

4. Indications for Use

510(k) Number (if known) : K073652

Device Name : ND LOWSPEED AIRMOTOR HANDPIECE (SEVERAL MODELS)
Model Number : MD-50M / MD-50B / MD-20M / MD-20B / MP-40M

Product Code : EFB

Any FDA Document numbers associated with prior formal correspondence with FDA : B000016

Indications for Use :

ND air powered low speed airmotor is used to power various U-type attachment which helps dental clinician perform the hygiene dentistry work. All the devices are autoclavable.

Prescription Use _____X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073652

4. Indications for Use

510(k) Number (if known) : K073652

Device Name : ND HIGHSPEED AIRTURBINE HANDPIECE (SEVERAL MODELS)
Model Number : TCP-450M / TCP-450B / TCP-350M / TCP-350B / TC-40PM / TC-40PB / TC-35YM / TC-35YB

Product Code : EFB

Any FDA Document numbers associated with prior formal correspondence with FDA : B000016

Indications for Use :

ND highspeed airturbine handpiece is an air-powered dental handpiece for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restoration and polishing teeth. All the devices are autoclavable.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073652

4. Indications for Use

510(k) Number (if known) : K073652

Device Name : ND E-TYPE STRAIGHT NOSECONE (SEVERAL MIDELS)
Model Number : ES-30A / ESG-30AR / MWS-30A

Product Code : EGS

Any FDA Document numbers associated with prior formal correspondence with FDA : B000017

Indications for Use :

ND straight nosecone is powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. ES-30A is E-type 1:1 ratio, ESG-30AR is E-type 4:1 ratio, and MWS-30A is Midwest-type 1:1 ratio. All the devices are autoclavable. They accept 2.35mm (3/32") standard burs and can have prophy angles mounted.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073652

4. Indications for Use

510(k) Number (if known) : K073652

Device Name : ND E-TYPE CONTRA ANGLE (SEVERAL MODELS)
Model Number : EC-20L / EC-30BL / EG-20L / EGG-20L

Product Code : EGS

Any FDA Document numbers associated with prior formal correspondence with FDA : B000017

Indications for Use :

ND e-type contra angle is powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. EC-20L and EC-30BL are 1:1 ratio, EG-20L is 4:1 ratio, and EGG-20L is 16:1 ratio. All of the devices are autoclavable.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073652

4. Indications for Use

510(k) Number (if known) : K073652

Device Name : ND U-TYPE PROPHYLAXIS ANGLE (SEVERAL MODELS)

Model Number : RA-10PS / RA-10PK / RA-50PS / RA-50PK / RA-10PS / RA-10PK / RA-50PS / RA-50PK / DC-10L / DU-20L / DU-20L

Product Code : EGS

Any FDA Document numbers associated with prior formal correspondence with FDA : B000017

Indications for Use :

ND u-type prophylaxis angle is used mounted on U-type nose attachment powered by either lowspeed airmotor or electric micromotor for hygiene dentistry work. All the devices are fully autoclavable.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073652